IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **Ruben** *et al.*

Application Serial No.: 09/774,639   Art Unit: 1634

Filed: February 1, 2001   Examiner: Myers, C.

For: Secreted Protein HBJFE12   Attorney Docket No.: PZ013P1C1
        (as amended)

Commissioner for Patents
Washington, D.C. 20231

Declaration of Dr. George Komatsoulis Under 37 C.F.R. § 1.132

I, George Komatsoulis, do hereby declare and say:

1.   I am a citizen of the United States, residing at 9518 Garwood Street, Silver Spring, MD, 20901.

2.   Since February 3, 1997, I have served as a scientist of Human Genome Sciences, Inc., 9410 Key West Avenue, Rockville, Maryland 20850, assignee of the captioned application.

3.   I have personal knowledge that the expression of the polynucleotide of SEQ ID NO:43 was assessed in hundreds of human tissues, including cancerous tissue (*e.g.*, B-cell lymphoma tissue), as well as many other "normal" (*i.e.*, non-cancerous) blood cells (*e.g.*, T cells, B cells, monocytes). Based on this assessment, no expression was observed in "normal" blood cells. In contrast, expression was observed in B-cell lymphoma tissue.

4.   I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States code and that such willful false statements may jeopardize the validity of the application of any patents issued thereupon.

_____
Dr. George Komatsoulis

_____
10 Jan - 2003
Date

☐ **1: AC004804. Homo sapiens 12p1...[gi:3406032]**   Links

```
LOCUS       AC004804               108879 bp    DNA     linear   PRI 16-SEP-1998
DEFINITION  Homo sapiens 12p13.3 PAC RPCI5-927J10 (Roswell Park Cancer
            Institute Human PAC library) complete sequence.
ACCESSION   AC004804
VERSION     AC004804.1  GI:3406032
KEYWORDS    HTG.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 108879)
  AUTHORS   Muzny,D., Arenson,A.D., Adams,C., Bunac,C., Carvelli,K., Chang,J.,
            Chacko,J., Chen,J., Ding,Y., Dugan,S., Durbin,J., Forcum,J.,
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            Vo,Q., Williamson,A., Worley,K.C., Yu,W., Kucherlapati,R.,
            Nelson,D. and Gibbs,R.A.
  TITLE     Direct Submission
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 108879)
  AUTHORS   Worley,K.C.
  TITLE     Direct Submission
  JOURNAL   Submitted (06-JUN-1998) Molecular and Human Genetics, Baylor
            College of Medicine, One Baylor Plaza, Houston, TX 77030, USA
REFERENCE   3  (bases 1 to 108879)
  AUTHORS   Worley,K.C.
  TITLE     Direct Submission
  JOURNAL   Submitted (09-JUL-1998) Human Genome Sequencing Center, Department
            of Molecular and Human Genetics, Baylor College of Medicine, One
            Baylor Plaza, Houston, TX 77030, USA
REFERENCE   4  (bases 1 to 108879)
  AUTHORS   Worley,K.C.
  TITLE     Direct Submission
  JOURNAL   Submitted (10-JUL-1998) Human Genome Sequencing Center, Department
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            Baylor Plaza, Houston, TX 77030, USA
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  AUTHORS   Worley,K.C.
  TITLE     Direct Submission
  JOURNAL   Submitted (08-AUG-1998) Human Genome Sequencing Center, Department
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REFERENCE   6  (bases 1 to 108879)
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  Score = 3170 (481.7 bits), Expect = 3.3e-143, Sum P(2) = 3.3e-143
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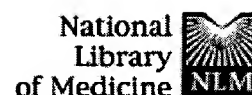
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Loss of genetic material from the short arm of chromosome 12 is a frequent secondary abnormality in non-Hodgkin's lymphoma.

Jonveaux P, Le Coniat M, Derre J, Vecchione D, Berger R.

Unite INSERM U 301, Institut de Genetique Moleculaire, Paris, France.

Abnormalities of the short arm of chromosome 12 have been detected in a wide variety of hematopoietic disorders. Seven cases of non-Hodgkin's lymphoma (NHL) are reported with various rearrangements involving bands 12p13 or 12p11, associated with other chromosome changes. A review of the literature confirms that rearrangements of 12p, mainly at band 12p13, are nonrandom chromosomal abnormalities in all subtypes of NHL, as in other malignant blood disorders. No common translocation could, however, be detected, and 12p abnormalities may be considered as secondary chromosomal events. Most of the 12p rearrangements involving translocation of genetic material of unknown origin, suggest that they result in loss of 12p segment.

PMID: 2050601 [PubMed - indexed for MEDLINE]

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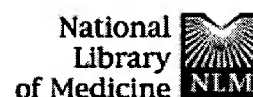
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☐ **1**: Genes Chromosomes Cancer 1997 Oct;20(2):155-66   Related Articles, Links

InterScience·

FISH identifies different types of duplications with 12q13-15 as the commonly involved segment in B-cell lymphoproliferative malignancies characterized by partial trisomy 12.

Dierlamm J, Wlodarska I, Michaux L, Vermeesch JR, Meeus P, Stul M, Criel A, Verhoef G, Thomas J, Delannoy A, Louwagie A, Cassiman JJ, Mecucci C, Hagemeijer A, Van den Berghe H.

Center for Human Genetics, University of Leuven, Belgium.

Clinical, cytogenetic, fluorescence in situ hybridization (FISH), and Southern blot data of 18 patients with different subtypes of B-cell non-Hodgkin's lymphoma, cytogenetically characterized by partial trisomy 12, are presented. These chromosomal changes occurred predominantly in clinically progressive chronic lymphocytic leukemia, mixed cell type, and advanced-stage follicle center cell lymphoma at the time of relapse or transformation into diffuse large cell lymphoma. Partial trisomy 12 consistently included the long arm of chromosome 12, either completely or partially, and resulted from dup(12q) or other rearrangements involving chromosome 12. The duplications were cytogenetically identified as dup(12) (q13q23), dup(12)(q13q22), or dup(12)(q13q15) in follicle center cell lymphoma or t(14;18)-positive diffuse large cell lymphoma; dup(12) (q13q22) or dup(12)(q13q24) in chronic lymphocytic leukemia; and dup(12) (q13q21) in a case of t(14;18)-negative diffuse large cell lymphoma. FISH, using library probes and a panel of YAC probes, mapped along the long arm of chromosome 12, confirmed the cytogenetic results in all cases analyzed except for three cases of t(14;18)-positive follicle center lymphoma or diffuse large cell lymphoma with dup(12q). In these cases, FISH showed similar, possibly identical, duplications, which involved a region more centromeric (12q11-21) than assumed by karyotypic analysis (12q13-22 or 12q13-23) and included alphoid DNA sequences, a combination hitherto unknown. In addition, commonly duplicated regions of chromosome 12 could be defined: 12q11-21, including alphoid DNA sequences for follicle center cell lymphoma or t(14;18)-positive diffuse large cell lymphoma, 12q13-22 for chronic lymphocytic leukemia, and 12p13-q15 for marginal zone cell lymphoma, all of which overlapped in 12q13-15. Whether these regions, especially 12q13-15, may contain genes which are important in

malignant transformation or disease progression of B-cell
lymphoproliferative malignancies characterized by complete or partial
trisomy 12 remains to be determined.

PMID: 9331566 [PubMed - indexed for MEDLINE]

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